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PROVISIONAL SPECIFICATION FOR THE INVENTION ENTITLED:

A Device for, and a Method of, Transcutaneous Pressure Waveform Sensing

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This invention is best described in the following statement:

A DEVICE FOR, AND A METHOD OF, TRANSCUTANEOUS PRESSURE WAVEFORM SENSING

Field of the Invention

The present invention relates to a device for, and a method of transcutaneous pressure waveform sensing. This is also sometimes referred to as arterial tonometry or transcutaneous blood pressure pulse waveform sensing.

Background of the Invention

Transcutaneous pressure waveform sensing involves applying a tonometer (ie. a pressure sensor) to the skin of a patient over a superficial artery, such as the radial artery. The tonometer is applied with enough downward force to applanate (ie. partially flatten) the artery. When applanated, the pressure pulses are no longer taken up circumferentially in the direction of applanation, but instead are transferred through the tissue in a radial direction to the interface between the skin and the small area of the tonometer above the artery where the intra-arterial pressure waveform can now be faithfully recorded. The varying force applied to the tonometer by the intra-arterial pressure pulse waveform is continuously converted into an electrical signal by a pressure transducer and plotted on a screen display which allows a clinician to examine the intra-arterial pressure waveform of the patient.Analysing the pressure pulse waveform using known appropriate software can provide diagnostic information to clinicians in relation to areas such as: stiffness of arteries; susceptibility to myocardial ischaemia; risk stratification of marginal hypertensives; and cardiovascular risk of type II diabetic patients.

A known device for transcutaneous pressure sensing, known as the Colin Medial CBM-7000 device, consists of a pressure pulse waveform detecting apparatus which is strapped around the wrist, a sphygmomanometer cuff which is wrapped around the arm, and a screen display. The pressure pulse wave detecting apparatus has a chamber housing a a semiconductor pressure sensor array . The pressure sensor array is positioned above the radial artery, and using hydraulic pressure, is pushed downwards to suitably flatten the artery. The amount of pressure applied to the sensor array is dependent on the output signal recorded by these sensors. A central processing unit (CPU) examines the output

signals and gives a signal to a pressure valve to either reduce or increase the downward pressure on the pressure sensor array. In other words, the CPU chooses the correct amount of pressure needed to applanate the artery sufficiently to obtain a strong arterial pressure waveform signal. A similar technique is used to correctly position the transducers just above the radial artery. More particularly, if a strong pressure waveform signal does not appear on any of the array of sensors, a servomotor will move the sensor array laterally until one of the sensors has a suitably strong signal, again with the CPU comparing all output signals from the transducers. This is a time consuming process. At the end of this operation, the output signal will resemble the intra arterial blood pressure waveform, but in an analogue voltage signal form . A sphygmomanometer cuff is then used to determine brachial artery systolic and diastolic pressure and the transducer pulse waveform is calibrated according to these values. The output monitor then displays a continuous and calibrated radial blood pressure waveforms. A disadvantage of this device is that it is complicated and time consuming to set up for a measurement. Another disadvantage is that the device is expensive initially, and has high in-service costsdue to the electro-mechanical complexity of the pressure sensor module that is attached to the wrist.

Another known device for transcutaneous pressure sensing, known as the Millar SPT-301 tonometer, is a hand-held pen-like device that contains a strain gauge on the end that converts a mechanical force into an electrical signal. For the tonometer to sense the arterial pressure, a downward force over the artery is manually applied by the user to flatten the artery. With this downward pressure, the pressure transducer on the end of the tonometer in contact with the skin will begin to sense the changing force resulting from the intra-arterial blood pressure pulsations. This tonometer is presently internationally accepted as the most accurate sensor for making transcutaneous arterial pressure waveform recordings. The size of the pressure sensing transducer in the Millar tonometer is very small and as a result it has the disadvantage that it has to be precisely positioned above the radial artery to achieve accurate results, which is difficult.. Another disadvantage of the Miller tonometer is that, because it is pencil-shaped, it flattens only a small area when the sensing end is pushed over the artery, and this can lead to the artery moving laterally out from under the sensor into the uncompressed area and so giving no arterial pressure waveform signal in the sensor.

Another known device for transcutaneous arterial pressure sensing, known as a Hypertension Diagnostics CD-2000 device, includes a fixed pressure sensor that is

strapped over the radial artery. The operator rotates a screw-threaded wheel to push the pressure sensor down over the artery and applanate the artery until a strong arterial pressure is recorded. The head of the device in contact with the skin is 1-1.5 cms in diameter. Disadvantages of the CD-2000 device are it is complicated and time consuming to set up for a measurement and it is expensive. Further, it has not been shown that this tonometer is able to faithfully reproduce the intra-arterial waveform.

It is an object of the present invention to substantially overcome or at least ameliorate one or more of the deficiencies of the prior art devices discussed above.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a device for transcutaneous pressure waveform sensing, the device including:

a pressure sensing head having a distal end; and

a collar extending at least partially around the head and having a distal surface, wherein the pressure sensing head distal end and collar are sized such that the pressure sensing head protrudes from the collar distal surface.

In use, when applied to a patient's skin over an underlying artery, at least some of the skin around the artery is flattened and depressed by the collar to a first depth and the skin over the artery is flattened and depressed by the pressure sensing head distal end to a second depth greater than the first depth.

In a second aspect, the present invention provides a method of transcutaneous pressure waveform sensing, the method including the steps of:

flattening and depressing at least some of the skin around an underlying artery and displacing same to a first depth; and

flattening and depressing the skin over the underlying artery and displacing same to a second depth greater than the first depth.

The skin around the artery is preferably compressed by the collar either side of the longitudinal direction of the artery (ie. the lateral sides). The width of the skin area flattened (and thus the width of the collar) either side of the artery, in a direction normal to the longitudinal direction of the artery, is is dependent upon the different physiology surrounding the specific artery (eg, radial, carotid, femoral). For the radial artery, it is desirable to compress about 3 times the unflattened width of the artery in each direction lateral to the direction of the artery

For the radial artery the difference between the first and second depth is preferably approximately 1.5-2.0mm .

For use with the radial artery, the collar is configured to be symmetrical in relation to the longitudinal direction of the artery and non-symmetrical in relation to a direction normal to the longitudinal direction of the artery, with the length of the collar from the pressure sensing head towards the patient's wrist being smaller than the length of the collar from the pressure sensing head towards the patient's elbow.

For use with the carotid artery, the collar is configured to be non-symmetrical in relation to the longitudinal direction of the artery and non-symmetrical in relation to a direction normal to the longitudinal direction of the artery, with the length of the collar from the pressure sensing head towards the front of the patient's throat being smaller than the length of the collar from the pressure sensing head towards the patient's neck and the length of the collar from the pressure sensing head towards the patient's shoulder being smaller than the length of the collar from the pressure sensing head towards the patient's head

The article entitled "Arterial Tonometry: Review and Analysis" by Gary M. et al (J. Biomechanics Vol. 16. No. 2. pp. 141-152, 1983) sets out the optimal width of the pressure sensing head relative to uncompressed artery diameter.. The preferred diameter of the pressure sensing head is less than or equal to the width of the flattened section of the underlying artery. However, for maximum flexibility in positioning the sensor, it is desirable to have the pressure sensing head as wide as possible (witness the limitations of the Millar sensor).

In one preferred form for the radial artery, the pressure sensing head is circular in cross section and the collar is annular in cross section, and the diameter of the pressure sensing head is approximately 3.5 mm.

Brief Description of the Drawings

A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 is a cross-sectional side view of an embodiment of a device for transcutaneous pressure waveform sensing according to the invention;

Fig. 2 is a top view of a collar used with the device shown in Fig. 1;

Fig. 3 is a bottom view of the collar shown Fig. 2;

Fig. 4 is a side view of the collar shown in Fig. 2;

Fig. 5 is a cross-sectional side view of the collar shown in Fig. 2;

Fig. 6 is a cross-sectional side view of the device shown in Fig. 1 without the collar;

Fig. 7 is a side view of the device shown in Fig. 6;

Fig. 8 is a top view of the device shown in Fig. 6;

Fig. 9 is a side view of the device shown in Fig. 6;

Fig. 10 is a bottom view of the device shown in Fig. 6;

Fig. 11 is a side view of the device shown in Fig. 1 over a patient's skin, prior to use; and

Fig. 12 is a side view of the device shown in Fig. 1, during use.

Description of the Preferred Embodiment

Referring to the drawings, there is shown a device 20 for transcutaneous pressure waveform sensing according to an embodiment of the present invention. The device 20 is comprised of a housing formed from a base 22 and top 24, which are both formed from poly vinyl chloride (PVC).

An internal chassis 26 within the base 22 supports a pressure transducer 28, in the form of a Pressure Sensor model No. MPX2300DT1, produced by the Motorola Company. The chassis 26 also includes an opening 30 which allows the sensor 28 to communicate pressure changes brought about in a pocket of gel 32, preferably dielectric silicone gel - grade 537 produced by the Dow Corning Company. The gel 32 is retained in the chassis 26 by a silicone boot 34, preferably of shore hardness 55.

The surface of the boot 34 that is denoted 36 represents the distal end of an overall "pressure sensing head" formed by components 28, 30, 32 and 34.

The device 20 also include an annular PVC collar 38 around the head, with a distal surface denoted 40. The collar has an external diameter of 13.6 mm and a thickness in the direction of axis 40 of 2.5 mm. The internal diameter of the collar is approximately 6 mm and is a snug fit around the cylindrical side wall of the boot 34. The collar 38 is an interference locating fit over the boot 34.

It is important to note that the distal end 36 of the pressure sensing head protrudes in the direction of axis 42 from the distal surface 40 of the collar 38.

As best shown in Fig. 8, the device 20 also include an electrical connection 44 which allow electrical signals generated by the HVPS 28 to be communicated to appropriate computer equipment and processing software, as is well known in the art and which will not be described further.

The operation of the device 20 will now be described with particular reference to Figs. 11 and 12. Fig. 11 shows the device 20 positioned over the skin 46 above the radial artery 48 of a human. Fig. 12 shows the device 20 after depression into the skin 46 to cause flattening of the artery 48. As the distal end 36 of the pressure sensing head protrudes from the distal surface 40 of the collar 38, the skin 46a adjacent the pressure sensing head is displaced about 2 mm more than the skin 46b adjacent the collar 38.

The correct amount of depression of the device 20 into the skin 46 is determined by the clinician manipulating the device 20 whilst watching a graphical representation of the intra-arterial pressure profile of the patient on a display screen (not shown). If the device 20 has not been depressed into the skin 46 far enough, a low amplitude and noisy pulse waveform signal will be evident. If the device 20 has been depressed too far into the skin 46 any pulse waveform signal will be lost due to the artery 46 being excessively flattened into occlusion. The clinician can determine when the device 20 has been optimally depressed into the skin 46 when a large amplitude pulse waveform signal is evident on the display screen.

The preferred embodiment of the device according to the invention is easier to operate and provides superior quality signals than prior art devices. This is because it allows the use of an optimally-sized pressure sensing head, which is able to pick up an

accurate signal from the applanated artery, that, due to the surrounding collar, does not need to be as accurately positioned to the centre of the underlying artery as prior art devices (eg, Millar tonometer). The latter is firstly becausethe reduced depression of the skin at least on the (lateral) sides of the artery assists in maintaining the preferred symmetrical position between the pressure sensing head and the artery by reducing movement of the artery laterally away from the pressure sensing head during applanation. Such movement is a particular problem when attempting to monitor the pressure of an artery with nearby collateral anatomy such as tendons and muscle etc. The partial depression of the skin lateral to the artery provides a stabilising pressure which maintains the artery in the optimal position relative to the pressure sensing head. Secondly, the width of the pressure sensing head is optimal for the underlying artery according to the Drzewiecki research, which is not the case for the prior art devices.

The preferred size and shape of the pressure sensing head and collar, and the amount by which the distal end of the head protrudes, are determined by trial and error and are dependent on the type, size and location of the superficial artery which is to be measured, and the anatomy surrounding the artery.

Although the invention has been described with reference to a preferred embodiment, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms. For example:

(a) the sensor may be hand-held or be hands-free with some wrist attachment mechanism;

(b) there may be some mechanical mechanism for applying the downward applanation pressure;

(c) the sensor may have fixed or replaceable collars;

(d) different collars may be chosen for the same artery site depending upon the depth of the artery below the skin in a particular patient;

(f) (e) there may be integrated into the sensor construction a mechanism for moving an adjustable-depth collar up and down to vary the height difference between the sensor and collar to an optimal height during the study;the pressure sensing area may be other than circular; and

(g) the pressure sensor may operate in a sensing method other than described here – for example, pressure may be sensed across the sensing area by piezo-electric sensor, by a strain-gauge pressure sensors, by a fibre optic pressure sensors, etc .

Dated 2 April 2002

AtCor Medical

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON

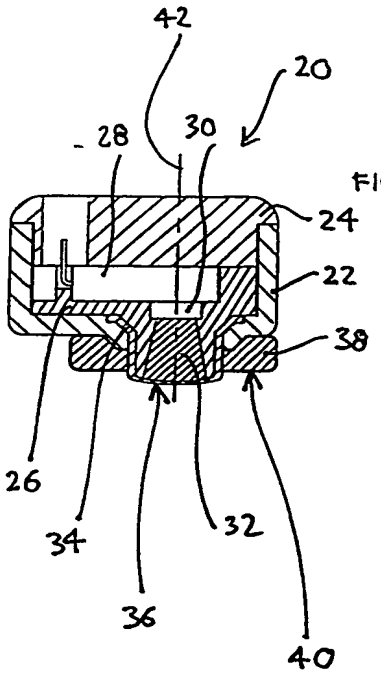

FIG. 1

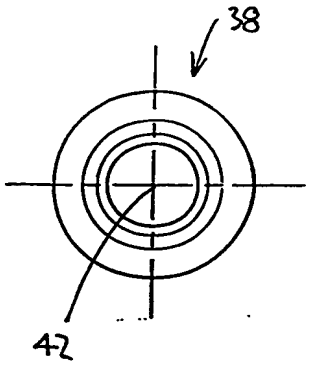

FIG. 2

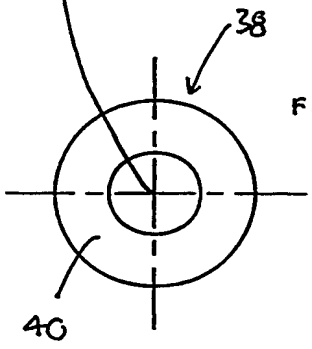

FIG. 3

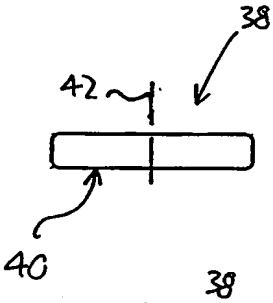

FIG. 4

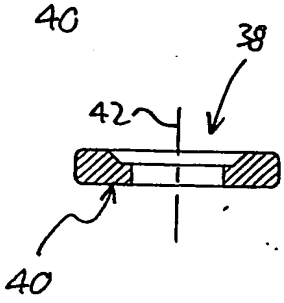

FIG. 5

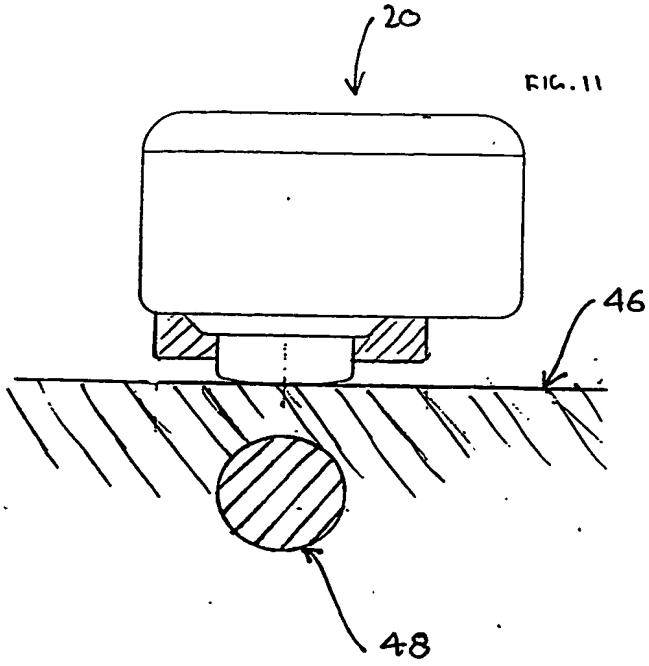

FIG. 11

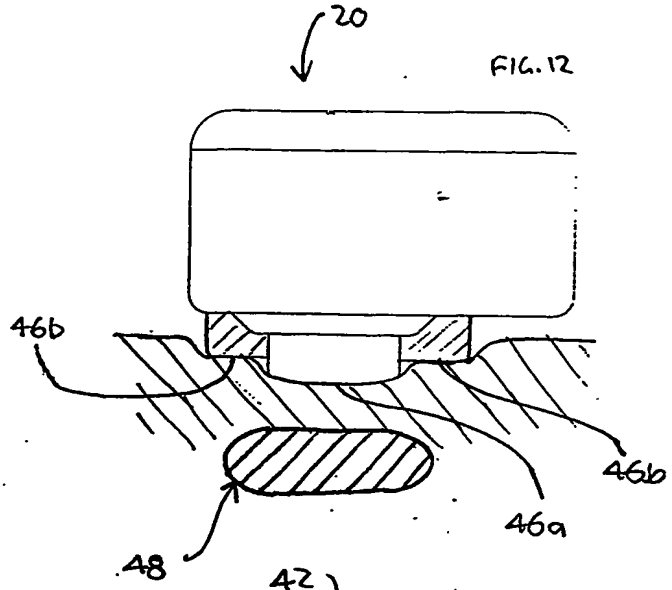

FIG. 12

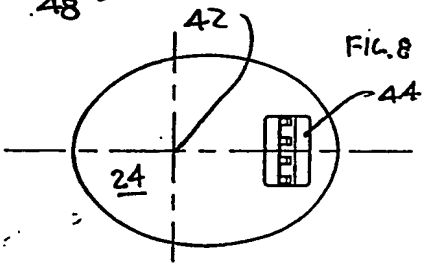

FIG. 8

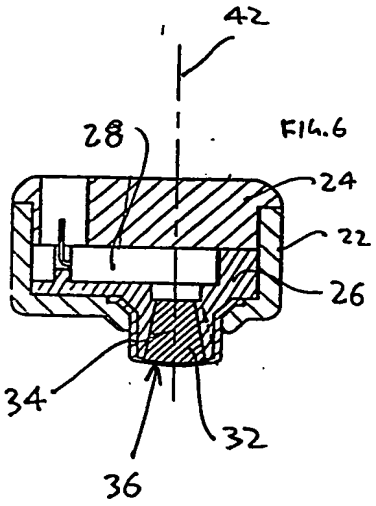

FIG. 6

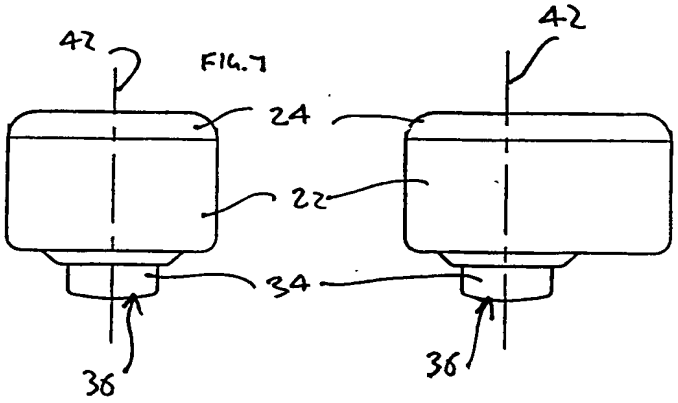

FIG. 7

FIG. 9

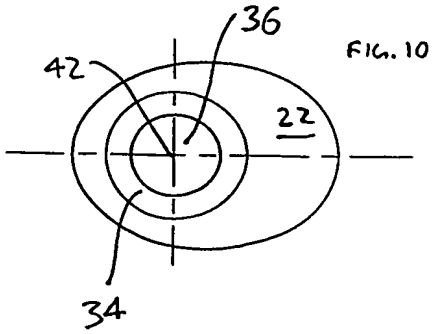

FIG. 10